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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/643,026

08/18/2003

Steven Vanhamel

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25559

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EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/643,026	Applicant(s) VANHAMEL ET AL.	
	Examiner Christopher P. Bruenjes	Art Unit 1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14, 18-31, 34 and 37-87 is/are pending in the application.
- 4a) Of the above claim(s) 50-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14, 18-31, 34, 37-49 and 80-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

WITHDRAWN REJECTIONS

1. The 35 U.S.C. 112 rejections of claims 1-11, 14, 17-31, 34, and 37-49 of record in the Office Action mailed December 28, 2005, Pages 2-7 Paragraphs 2-3, have been withdrawn due to Applicant's amendments in the Paper filed March 28, 2006.

2. The 35 U.S.C. 102 rejections of claims 1, 2, 5, 6, 10, 14, 17-22, 25-26, 30, 34, 37-41, and 43-46 as anticipated by Hirsch of record in the Office Action mailed December 28, 2005, Pages 8-12 Paragraph 4, have been withdrawn due to Applicant's amendments in the Paper filed March 28, 2006.

3. The 35 U.S.C. 102 rejections of claims 1, 2, 5-11, 17-22, 25-31, 40, and 43-46 as anticipated by Anderson of record in the Office Action mailed December 28, 2005, Pages 12-17 Paragraph 5, have been withdrawn due to Applicant's amendments in the Paper filed March 28, 2006.

4. The 35 U.S.C. 103 rejections of claims 3, 4, 23, and 24 over Hirsch in view of Brown of record in the Office Action mailed March 7, 2005, Pages 11-12 Paragraph 6, have been

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withdrawn due to Applicant's amendments in the Paper filed March 28, 2006.

5. The 35 U.S.C. 103 rejections of claims 7-9, 11, 27-29, 31, 42, and 47-49 over Hirsch in view of Anderson of record in the Office Action mailed March 7, 2005, Pages 12-15 Paragraph 7, have been withdrawn due to Applicant's amendments in the Paper filed March 28, 2006.

6. The 35 U.S.C. 103 rejections of claims 3, 4, 23, and 24 over Anderson in view of Brown of record in the Office Action mailed March 7, 2005, Page 16 Paragraph 8, have been withdrawn due to Applicant's amendments in the Paper filed March 28, 2006

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 18-21 are dependent on cancelled claim 17. The claims are therefore in definite because it is not understood what the full scopes of the claims are.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1, 2, 5, 6, 10, 14, 18-22, 25-26, 30, 34, 37-41, 43-46, and 80-87 are rejected under 35 U.S.C. 103(a) as being

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unpatentable over Hirsch et al (USPN 4,055,672) in view of Hester et al (USPN 4,539,836).

Regarding claims 1 and 22, Hirsch et al anticipate a packaging article (col.2, 1.1-5) comprising a base member (reference number 12, 44, or 12'' in Figures 1, 3, or 5 respectively). The packaging article further comprises a lid or front wall (reference number 14, 42, or 14'' in Figures 1, 3, or 5 respectively) comprising a first sheet of a porous material (reference numbers 22, 46, or 22'' in Figures 1, 3, or 5 respectively) and a second sheet (reference numbers 24 and 26 combined, 48 and 50 combined, or 24'' in Figures 1, 3, or 5, respectively). The first sheet is joined along at least a first edge portion thereof to the base member to define an enclosed interior volume (Figures 1, 3, or 5). Hirsch et al teach that the outer gas barrier or second sheet is polyethylene in combination or co-extruded with polyester, nylon, cellophane, polypropylene, polyvinyl acetate, or saran, and that the layer must be gas impermeable (col.4, 1.56-62). The peelable film of Hirsch et al, whether it be the second layer itself as shown in Figure 5 or a separate adhesive layer as shown in Figures 1 and 3, comprises polyethylene copolymerized with other materials but the adhesive is still peelable. Hirsch et al teach that the second layer is overlying, in contact with, and sealed to the

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first layer via a peelable adhesive (reference number 26, Figure 1 or reference number 50, Figure 3) or direct weld of reference numbers 24'' and 22''. The second layer is non-porous to passage of gas therethrough and comprises a peelable film in contact with the first layer of porous material, and the peelable film permits the peel removal of the second layer from the first layer to expose the first layer of porous material for passage of gas therethrough (see abstract). Regarding specifically claim 22, the limitation "useful for pressurization integrity testing and after pressurization integrity testing being permeable to sterilant gas for sterile packaging of a product article disposed therein" receives little patentable weight because it is a functional limitation in an article claim. Although every limitation is given consideration, articles are defined by what the article is, not what the article does. See MPEP 2114. In this case, Hirsch et al anticipate the structural limitations of claim 22 and the packaging article is capable of being used for the same purpose . claimed in claim 22 because it has a permeable layer and a peel removable impermeable layer overlying and sealed to the permeable layer for removal to expose the permeable layer to passage of gas.

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Hirsch et al fail to teach a pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume. However, Hester et al teach that sealed containers for perishable goods such as the package of Hirsch et al must include in the manufacturing process a means for testing package integrity to insure product quality (col.1, 1.9-12). Hester et al goes on to teach a rapid and reliable method for testing package integrity, which overcomes the deficiencies of other testing methods (col.2, 1.6-8). Hester et al teach that the package integrity is tested by inserting a pressurized gas into the enclosed interior volume of the package to be tested and if the seal stays in tack the positive pressure will overcome the negative pressure applied to the package in the apparatus and the package will eject and it will be determined that the package integrity is sufficient (col.2, 1.23-41). In order to perform this method of testing on the package a pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume is formed (col.4, 1.23-26). Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to apply a pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume of a package in order to test the seal integrity

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of the package, which must be included in a manufacturing process of any package being used to contain perishable goods, as taught by Hester et al.

Thus, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to form a pressurization gas inlet adapted to permit the ingress of pressurization gas to the enclosed interior volume on the packaging material of Hirsch et al, in order to test the seal integrity of the package, as taught by Hester et al, which, as taught by Hester et al, is a necessary step in any manufacturing process of a package being used to contain perishable goods, in which Hirsch et al is.

Regarding claims 2, 5-6, 10, 25-26, and 30, Hirsch et al teach that the first layer comprises polyethylene (col.4, 1.34-43).

Regarding claims 14 and 34, Hirsch et al teach that the second layer is comprised of impermeable materials such as polyester, nylon, cellophane, polypropylene, polyvinyl acetate, or saran in combination with polyethylene (col.4, 1.56-65).

Regarding claims 18 and 37-41, Hirsch et al teaches that the multilayer web in one embodiment is a lid material for a tray package, in which the tray is formed of a non-porous structural component (reference number 12, Figure 1) in the form

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of a sheet or shaped member (Figure 1) and in a second embodiment the multilayer web is a wall or structural component of a bag adapted to hold a product article therein (col.3, 1.10-13 and Figure 3).

Regarding claims 19-21 and 43-46, the limitations regarding the properties and type of product article packaged in the multilayer web article receives little patentable weight, because they are intended use limitations. Articles are defined by what the article is, not what the article does. In this case, the article of Hirsch et al based on the structure of the article would be capable of being used to package an article that must be sterile, a medical device, or pharmaceutical agent, and therefore Hirsch et al anticipate claims 19-21 and 43-46.

Regarding claims 80 and 84, the term "spout" is given its broadest reasonable interpretation, which is an opening in which something can be poured out of a sealed interior volume. In this case, the opening of Hester et al is an opening in which something could be poured out of the sealed interior volume of the package.

Regarding claims 81 and 85, it would have been obvious to one having ordinary skill in the art to form a gland over the pressurization gas inlet in order to ensure that the pressurized gas being applied to the interior volume is only able to enter

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into the package and not substantially leave the package because otherwise the opening itself would allow the gas to escape too quickly for the positive pressure to overcome the negative pressure during the testing phase.

Regarding claims 82 and 86, Hester et al teach that the opening is connected to the central bore of the testing head so the gas inlet comprises an inlet connector element.

Regarding claims 83 and 87, Hester et al teach that the gas inlet is formed in the body of the package and it would have been obvious to one having ordinary skill in the art at the time of Applicant's invention that the inlet would be formed in the base member of the Hirsch et al package because the lid portion of the package is a specialized system and one of ordinary skill in the art would have recognized that the inlet would be formed in the less complex portion of the package.

12. Claims 3-4 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al in view of Hester et al as applied to claims 2 and 22 above, and further in view of Brown et al (USPN 5,217,772).

Hirsch et al and Hester et al taken as a whole teach all that is claimed in claims 2 and 22 as presented above, but fail to teach the first layer being formed of a cellulosic material

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such as paper. However, Hirsch et al teach that the first layer is formed of any gas permeable material having a suitable gas transmission rate of types which are well known in the art (col.4, 1.34-44). Brown et al teach that well known permeable materials having a suitable gas transmission rate while remaining impermeable to bacteria and microorganisms, which would be a concern in food packaging, include fibrous layers (col.1, 1.10-26). In particular, TYVEK and paper, which is a cellulosic material, are well known fibrous layers that meet the requirements of the gas permeable material used in Hirsch et al while remaining impermeable to bacteria and microorganisms. One of ordinary skill in the art would have recognized that Hirsch et al and Brown et al are analogous art insofar as both references are concerned with using combinations of permeable and non-permeable layers to preserve easily contaminated products during storage and transportation of the products within the packages.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to substitute the cellulosic paper gas permeable layer of Brown et al for the gas permeable layer of Hirsch et al because paper is a well known material used in the formation of gas permeable layers within peelable packages, and one of ordinary

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skill in the art would have selected the appropriate gas permeable layer from well-known gas permeable layers depending on the intended end result of the product, as taught by Hirsch et al. Specifically, one of ordinary skill in the art would have chosen a cellulosic paper when impermeability to bacteria and microorganisms is a concern, as taught by Brown et al.

13. Claims 7-9, 11, 27-29, 31, 42, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirsch et al in view of Hester et al as applied to claims 1, 6, 22, 26, and 41 above, and further in view of Anderson et al (USPN 5,418,022).

Hirsch et al and Hester et al taken as a whole teach all that is claimed in claims 1, 6, 22, 26, and 41 as presented above, and teaches that the peelable film comprises a polyethylene film as shown above. Regarding claim 47, Hirsch et al also teach that the sheet form structural component is bonded at an edge region of said first layer to a non-porous panel to form therewith an enclosed interior volume for holding said product article (Figure 1 or 3), and teach that the second layer comprises a peelable polyethylene film (col.4, 1.56-65) and that the non-porous panel is formed of polyethylene film (col.3, 1.52-62).

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Hirsch et al and Hester et al combined fail to teach that the first film is formed of a fibrous material of high-density polyethylene such as TYVEK. However, Hirsch et al teach that the first layer is formed of any gas permeable material having a suitable gas transmission rate of types which are well known in the art (col.4, l.34-44). Anderson et al teach that well known permeable materials having a suitable gas transmission rate while remaining impermeable to bacteria and microorganisms, which would be a concern in food packaging, include fibrous layers specifically TYVEK (see abstract and col.2, l.57-65). Anderson et al further teach that TYVEK is a spunbonded olefin sheet of high density polyethylene fibers formed by flash spinning continuous strands of ultrafine interconnected fibers, dispersing them onto a moving belt and then bonding them together with heat and pressure into a multi-layer sheet (col.1, l.15-25). One of ordinary skill in the art would have recognized that Hirsch et al and Anderson et al are analogous art insofar as both references are concerned with using combinations of permeable and non-permeable layers to preserve easily contaminated products during storage and transportation of the products within the packages.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was

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made to substitute the TYVEK gas permeable layer of Anderson et al for the gas permeable layer of Hirsch et al because TYVEK is a well known material used in the formation of gas permeable layers within peelable packages, and one of ordinary skill in the art would have selected the appropriate gas permeable layer from well-known gas permeable layers depending on the intended end result of the product, as taught by Hirsch et al.

Specifically, one of ordinary skill in the art would have chosen TYVEK when impermeability to bacteria and microorganisms is a concern, as taught by Anderson et al.

Regarding claims 48 and 49, Hirsch et al and Hester et al combined fail to teach the bond strength between the first layer and the non-porous panel or the second layer. However, Hirsch et al teach that the first and second layers are adhesively joined in such a fashion that the second layer and the adhesive are peelable from the first layer in such a fashion that, upon peeling, an integral package comprising the tray having the inner permeable layer of the lid heat sealed thereto remains intact and allows the package contents to be exposed to the atmosphere (col.2, 1.56 - col.3, 1.9). One of ordinary skill in the art would have recognized that the seal strength between the first and second layer must be strong enough to remain sealed during transportation and storage of the article but weak enough

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to easily peel the second layer from the first layer and that the bond strength between the first layer and the non-porous panel must be substantially greater than the seal strength between first and second layer so that when the second layer is peel the first layer does not separate from the non-porous panel, as taught by Hirsch et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time Applicant's invention was made to select the bond and sealing strengths between the first layer and the second layer and non-porous panel respectively in the ranges taught in claims 48 and 49, because the requirements presented for the bond and seal strengths in Hirsch et al are the same requirements as the claimed invention. Thus, through routine experimentation one having ordinary skill in the art at the Applicant's invention was made would have arrived at the same ranges of bond and sealing strengths as the claimed invention, absent the showing of unexpected result.

Response to Arguments

14. Applicant's arguments with respect to claims 1-11, 14, 18-31, 34, and 37-49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.' Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P. Bruenjes whose telephone number is 571-272-1489. The examiner can normally be reached on Monday thru Friday from 8:00am-4:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB

May 10, 2006


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

5/10/06